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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,484	02/17/2004	David B. Rozema	Mirus.030.16.04	2135
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Mark K. Johnson Mirus Corporation 505 S. Rosa Rd. Madison, WI 53719			EXAMINER EPPS FORD, JANET L	
			ART UNIT	PAPER NUMBER
			1633	
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			08/08/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/780,484

Applicant(s)

ROZEMA, DAVID

Examiner

Janet L. Epps-Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-7 and 10-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-7 and 10-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6-05-07 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1, 3-7, and 10-20 are presently pending.

### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 112***

4. The rejection of claims 5-7 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in response to Applicant's amendment filed 6-05-07.

#### ***Claim Rejections - 35 USC § 102***

5. Claims 1, 3-7, 10-16 and 19-20 remain rejected under 35 U.S.C. 102(e or a) as being anticipated by Pinchuk et al. (US 2002/0107330), for the reasons of record.
6. Applicant's arguments filed 6-05-2007 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that Pinchuk et

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al. does not teach reversible modification of amines on a polyvinylether polymer by attachment of functional groups via pH labile covalent bonds. Contrary to Applicant's assertions, it is noted that only claims 6 and 16 recite wherein the polyamine of the instant claims is limited to a polyvinylether. Pinchuk et al. at paragraph [0205], discloses wherein the polymers of their invention include the following classes: "polycarboxylic acids, including polyacrylic acid; cellulosic polymers, including cellulose acetate and cellulose nitrate; gelatin; *polyvinylpyrrolidone*; cross-linked *polyvinylpyrrolidone*; polyanhydrides including maleic anhydride polymers; polyamides; *polyvinyl* alcohols; copolymers of vinyl monomers such as EVA (ethylene-vinyl acetate copolymer); ***polyvinyl ethers***; polyvinyl aromatics." Moreover, Pinchuk et al. at paragraph [0198] teach that "[T]he therapeutic agent can also be covalently bonded, hydrogen bonded, or electrostatically bound to the copolymer. As specific examples, nitric oxide releasing functional groups such as ***S-nitroso-thiols*** can be provided in connection with the copolymer, or the copolymer can be provided with charged functional groups to attach therapeutic groups with oppositely charged functionalities." Absent evidence to the contrary polymers comprising the thiol based modifications taught by Pinchuk et al. read on the pH labile modifications recited in the instant claims.

Therefore, contrary to Applicant's opinion, the instant claims remain rejected for the reasons of record.

7. Claims 1-5, 7-15, 17, and 19-20 remain rejected under 35 U.S.C. 102(b) as being anticipated by Wolff et al. (US 20010036926), for the reasons of record.

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8. Applicant's arguments filed 6-05-2007 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that Wolff et al. does not teach the reversible modification of any amines or the reversible modification of a membrane active polyamine. Contrary to Applicant's assertions, as stated in the prior Office action, Wolff et al. teach that "[t]he monomers used for polymerization can also contain **chemical moieties that can be modified** before or after the polymerization including (but not limited to) **amines** (primary, secondary, and tertiary), amides, carboxylic acid, ester, hydroxyl, hydrazine, alkyl halide, aldehyde, and ketone. (see paragraph [0103]). Polyethyleneimine and polylysine were used in specific examples to form complexes with nucleic acid via a disulfide linkage, see examples 4 and 5. Therefore, contrary to Applicant's assertions, the teachings of Wolff et al. read on the instant claims as amended.

9. Claims 1-5, 7-15, 17 and 19-20 remain rejected under 35 U.S.C. 102(e) as being anticipated by Wolff et al. (US 7,087,770), for the reasons of record.

10. Applicant's arguments filed 6-05-2007 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that Wolff et al. does not teach the reversible modification of any amines or the reversible modification of a membrane active polyamine. Contrary to Applicant's assertions, Wolff et al. teach the following in the Summary (see col. 2) of their invention:

Described in a preferred embodiment is a process for the delivery of a compound to a cell, comprising associating a compound, containing a disulfide bond that can be cleaved under physiological conditions, with a polymer, then delivering the polymer to the cell. The polymer may comprise a first polymer and a second polymer. The first polymer and the second polymer may comprise nucleic acids, proteins, genes, antisense polymers, DNA/RNA hybrids, or

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synthetic polymers.

In another preferred embodiment, a biologically active compound is associated with a disulfide-containing compound, comprising: the disulfide-containing compound having a labile disulfide bond that is selected from the group consisting of (a) a disulfide bond that is cleaved more rapidly than oxidized glutathione and (b) a disulfide bond constructed from thiols in which one of the constituent thiols has a lower pKa than glutathione and (c) a disulfide bond that is activated by intramolecular attack from a free thiol.

In one specific embodiment, Wolff et al. discloses wherein a transduction signal is used to transport a covalently linked molecule across a membrane of a cell. The transduction signal used is a peptide, and the molecule is a nucleic acid, the peptide is then linked to said nucleic acid via a reversible activated disulfide bond, see claims.

Absent evidence to the contrary the disclosure of Wolff et al. anticipates the instant claims.

### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-5, 7-15, and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff et al. in view of Blazyk (WO 200160162 A2; see disclosure of US 20040249122 A1).

In one specific embodiment, Wolff et al. discloses wherein a transduction signal is used to transport a covalently linked molecule across a membrane of a cell. The

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transduction signal used is a peptide, and the molecule is a nucleic acid, the peptide is then linked to said nucleic acid via a reversible activated disulfide bond, see claims.

The discussion Wolff et al. (US 7,087,770) is incorporated here. However, Wolff et al. does not teach wherein the peptide is pardaxin.

Blazyk describe pardaxin as an amphipathic peptide having membrane disrupting activity.

It would have been obvious to the ordinary skilled artisan at the time of the instant invention to modify the teachings of Wolff et al. with the teachings of Blazyk in the design of the instant invention. One of ordinary skilled in the art would have been motivated to make this modification since the pardaxin peptide of Blazyk is an amphipathic polymer, as recited in instant claim 7, and is therefore considered a structurally and functionally equivalent peptide according to the instant invention. It would have been obvious to the person of ordinary skill in the art seeking alternative compositions according to the present invention, to substitute one functionally equivalent amphipathic polymer according to the present invention with a prior art amphipathic polymer, with the expectation that the composition produced would have the same functional properties as the claimed composition.

### ***Double Patenting***

13. Claims 1-5, 7-15, 17 and 19-20 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 7,087,770, for the reasons of record.

Applicant's arguments filed 6-05-2007 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that Wolff et al. does not teach the reversible modification of any amines or the reversible modification of a membrane active polyamine. Contrary to Applicant's the instant claims recite wherein a transduction signal is used to transport a covalently linked molecule across a membrane of a cell. The transduction signal used is a peptide, and the molecule is a nucleic acid, the peptide is then linked to said nucleic acid via a reversible activated disulfide bond, see claims.

14. Claim 18 is also rejected on the ground of nonstatutory obvious-type double patenting as being unpatentable over Wolff et al. in view of Blazyk (WO 200160162 A2), for the reasons given above, and in the rejection under 35 USC 103(a) over Wolff et al. in view of Blazyk as set forth above.



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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/  
Primary Examiner  
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JLE